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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,603	01/26/2001	Arthur E. Schwartz	20076-53	8546

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EXAMINER

RAM, JOCELYN DEBRA

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,603

Applicant(s)

SCHWARTZ, ARTHUR E.

Examiner

Jocelyn D Ram

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "third tubular member" must be shown or the feature canceled from the claim. No new matter should be entered. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference signs not mentioned in the description: Fig. 11, 157, 160, 162, 164, 170, 172, 174, 176, 178, 180, 182, 184, 186 and 188. A proposed drawing correction, corrected drawings, and/or amendment to the specification to add the reference signs in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: The brief description of the drawings does not include a description of Fig. 11. It also appears that the description of the figures is mis-numbered, namely, "Fig. 8" should be changed to -Fig. 9--; "Fig. 9" should be changed to -Fig. 10--; and "Fig. 10" should be changed to -Fig. 11--. With the corrected numbering as mentioned above, it appears that there is a description missing for Fig. 8. Additionally, page 7, line 26-7 and page 8, line 10 "Fig.

8" should be changed to -Fig. 9--; page 8, line 18, "Fig. 9" should be changed to -Fig. 10-; page 10, line 4, "Fig. 10" should be changed to -Fig. 11--. Reference numeral "84" is referred to as both "insulation member" and "inflation member"; it is required that consistent language be used to avoid confusion. Appropriate correction is required.

Claim Objections

Claim 30 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 30 provides no further structural limitations on the catheter, as the statement that the catheter is useful for brain cooling is merely functional and therefore has limited patentable weight.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 recites the limitations "the distal direction" in line 11-12 and "the elongated external member" in line 13; claim 21 recites the limitation "the entire length" in line 2. There is insufficient antecedent basis for these limitations in these claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-28, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Saab (5,624,392). Saab shows a catheter (10) for intravascular corporeal cooling comprising: an elongated tubular member (12) having proximal and distal sections, an outer surface, and at least one lumen (11) extending therethrough, and annular insulation (16, 22) having proximal and distal ends arranged concentrically (Fig. 1) around the outer surface of the elongated tubular member (12) is insulated from fluid or tissue external to the annular insulation (16, 22), wherein the insulation is tapered (at 18), extends along substantially the whole length or a shorter section of the catheter (col 16, lines 54-59) and comprises a fluid-filled member, filled with gas, water or saline (col 9, line 66 - col 10 line 2) and polymeric material (14, 20, col 10, lines 38-39). Regarding claim 30, the structure can be used for brain cooling.

Claims 20-24, 27 and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Ginsburg (6,033,383). Ginsburg shows a catheter for intravascular corporeal cooling comprising: an elongated tubular member (20) having proximal (24) and distal (26) sections, an outer surface, and at least one lumen (28) extending therethrough, and annular insulation (18, 32, 34) having proximal and distal ends arranged concentrically (Fig. 2) around the outer surface of the elongated tubular member (20) is insulated from fluid or tissue external to the annular insulation (col 6, lines 6-13), wherein the insulation is tapered (Fig. 11) and comprises a fluid-filled member, and at least one lumen is in communication with a source of cooled blood and/or a liquid pharmaceutical source (col 4, lines 1-13), which can be used for brain cooling (col 4, line 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg in view of Donlon (6,056,723). Ginsburg shows all of the limitations of claim 29 except

Art Unit: 3739

for the pressure sensor. Donlon shows a similar catheter for placement in a blood vessel which includes a pressure sensor (38). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a pressure sensor in the device of Ginsburg to prevent injury by which can be caused by high pressure fluids in the bloodstream.

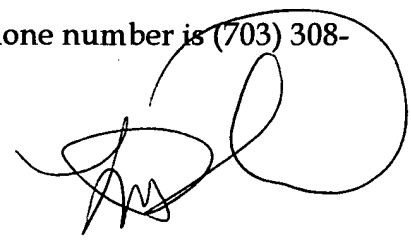
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Boussignac et al. (5,000,734) shows a catheter with a balloon which includes lumens for allowing blood to pass through. Gobin et al. (6,126,684) shows a heat exchange catheter, including multiple balloons. Werneth (6,325,818) shows a cooling catheter that includes blood passageways through the balloon. Hussein et al. (4,445,892) is a dual balloon catheter. Sahota (5,019,042) and Jang (4,990,139) show multiple balloon catheters, wherein the insulation is a fluid. Bertolero et al. (5,868,703) shows a multichannel catheter with an insulating balloon on the distal end and a lumen in communication with a liquid drug source.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jocelyn D Ram whose telephone number is (703) 308-6392. The examiner can normally be reached on Mon-Fri, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700

JR
June 7, 2002